

# **EXHIBIT 2**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

<b>IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</b>	<b>Civil Action No. 19-md-2875</b>  <b>HON. ROBERT B. KUGLER</b>
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**DEFENDANTS' NOTICE OF SUBPOENA**

PLEASE TAKE NOTICE that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, Defendants in the above captioned action, by and through the undersigned counsel, will serve a subpoena for the production of documents for the attention of Jessica Davidson Miller, Skadden, Arps, Slate, Meagher & Flom LLP, One Manhattan West, New York, NY 10001 by 9:00 a.m. ET on December 28, 2022, a copy of which is attached hereto, on Valisure LLC, to its registered agent, David Light, 5 Science Park, New Haven, CT 06511.

Dated: December 14, 2022

Respectfully submitted,

By: /s/ Jessica Davidson Miller

Jessica Davidson Miller (DC Bar No. 457021)

*Liaison Counsel for Manufacturer Defendants*

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*Attorney for Defendants Zhejiang Huahai  
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Princeton Pharmaceutical Inc., and Solco Healthcare  
US, LLC*

To:

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AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the  
District of New Jersey

\_\_\_\_\_  
*Plaintiff*

v.

In re Valsartan, Losartan, and Irbesartan Products  
Liability Litigation

\_\_\_\_\_  
*Defendant*

)  
)  
) Civil Action No. 19-md-2875  
)  
)  
)

**SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS  
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION**

To: Valisure LLC, 5 Science Park, New Haven, CT 06511

\_\_\_\_\_  
*(Name of person to whom this subpoena is directed)*

☒ **Production:** **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Attachment A.

Place: Skadden, Arps, Slate, Meagher & Flom LLP,  
One Manhattan West, New York, NY 10001  
Attn: Jessica Davidson Miller

Date and Time:

12/28/2022 9:00 am

☐ **Inspection of Premises:** **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:

Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 12/14/2022

CLERK OF COURT

OR

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

/s/ Jessica Davidson Miller

\_\_\_\_\_  
*Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc, who issues or requests this subpoena, are: Jessica Davidson Miller, 1440 New York Avenue, N.W. Washington, D.C. 20005, jessica.miller@skadden.com, (202) 371-7000

**Notice to the person who issues or requests this subpoena**

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Page 2)

Civil Action No. 19-md-2875

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*

I received this subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_.

☐ I served the subpoena by delivering a copy to the named person as follows: \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_  
\_\_\_\_\_.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_  
\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc.:

## Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

### (c) Place of Compliance.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
  - (i) is a party or a party's officer; or
  - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

### (d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

### (e) Duties in Responding to a Subpoena.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) *Contempt.*

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.



## **ATTACHMENT A**

### **Definitions and Instructions**

1. “Valisure,” “You,” or “Your,” means Valisure LLC and ValisureRX LLC, inclusive of its officers, directors, employees, partners, principals, members, agents, representatives, attorneys, parents, subsidiaries, affiliates, related entities, assigns, predecessors-in-interest, successors-in-interest, and every person or entity acting or who has ever acted on its behalf.

2. “FDA” means the United States Food and Drug Administration.

3. “NDC” means National Drug Code, as maintained by FDA in its National Drug Code Directory of finished drug products, unfinished drugs and compounded drug products.

4. “Citizen Petition” means the June 13, 2019 Citizen Petition, including Appendix A thereto, submitted by Valisure to FDA related to certain testing performed by Valisure on specific lots of the angiotensin II receptor blocker valsartan.

5. “Novartis Product” means any drug or combination drug containing valsartan, including brand name drugs, manufactured, distributed, marketed, and/or sold by Novartis, as identified in the Citizen Petition.

6. “Document” shall have the broadest meaning permitted under the Federal Rules of Civil Procedure and include, without limitation, all writings of any kind, including the originals and all non-identical copies, whether different from the original by reason of any notation made on such copies or otherwise, including, without limitation, paper documents of any kind, communications, correspondence, memoranda, notes, diaries, statistics, letters, electronic mail, text messages, electronic files of any type or nature, all other forms of electronic communication, telegrams, minutes, contracts, reports, studies, text, statements, receipts, returns, summaries, pamphlets, books, prospectuses, inter-office and intra-office communications, offers, notations or recordings of any sort regarding conversations, telephone calls, meetings or other communications, bulletins, printed matters, computer printouts, teletypes, telefax, invoices, worksheets, and each and every electronic or paper draft, alteration, modification, change or amendment of any kind of the foregoing; graphic or aural records and oral representations of any kind, including, without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings, motion pictures; and electronic, magnetic, mechanical or electric records or representations of any kind, including, without limitation, tapes, cassettes, disks, computer generated or stored information and recordings. The term “Document” expressly includes electronic or magnetic data, which should be produced in its unaltered, native-file format in which such data is ordinarily kept. All documents should be produced without alteration and with any and all exhibits and attachments thereto. The term “Document” is inclusive of the term “Communication” and all electronically stored information, as referenced in Federal Rule of Civil Procedure 34.

7. You are required to produce all responsive documents that are within Your possession. The potential availability of any Document by way of public record access,

authorization for release, or via another source does not excuse Your obligation to produce materials in Your possession.

8. You must respond in writing and separately to each request. If no such Documents are within Your possession, custody or control, so state affirmatively. If You are aware that responsive documents exist but are outside of Your possession, custody, or control, identify the persons or entities with possession of such documents.

9. This Subpoena seeks only non-privileged information. However, if any Document(s) responsive to this Subpoena is withheld on the basis of such privilege, a privilege log shall be provided that complies with the privilege log requirements of the Electronic Discovery Protocol in this case [ECF No. 127].

10. This Subpoena is being served for the purposes of discovery and is not to be taken as waiving any objections to the introduction of evidence on subjects covered by this Subpoena, or as an admission of the relevance or materiality of any of the matters covered by this Subpoena.

11. Any Documents produced in response to this Subpoena may be designated in accordance with the Confidentiality and Protective Order in this case [ECF No. 139].

#### **Documents Requested**

Please produce the following Documents that are in your possession, custody, or control:

1. Documents sufficient to identify the NDC of all Novartis Product referenced in the Citizen Petition submitted by Valisure to FDA.